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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,587	02/12/2002	Douglas E. Brenneman	15280W-0021US	9701
7590 10/19/2006			EXAMINER	
Annette S Parent Townsend and Townsend and Crew Two Embarcadero Center 8th Floor San Francisco, CA 94111-3834			STANDLEY, STEVEN H	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/049,587	Applicant(s) BRENNEMAN ET AL.	
	Examiner Steven H. Standley	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 7, 10-41 and 54-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9 and 42-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendment filed 8/10/06 has been made of record. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action. Claims 1-6, 8-9, and 42-53 are under consideration. Applicant is reminded that now claims 46-52 are directed to non-elected species (ADNFIII plus ADNFI). See the objection on page 3 (number 4) of the prior office action.

Objections/Rejections: Withdrawn

Specification

Objection to the specification for embedded hyperlinks is withdrawn due to applicant's amendment.

Claim Objections

Objection to claim 5 is withdrawn due to applicant's amendment.

Objections/Rejections: Maintained/New Grounds

Claim Objections

Objection to claims 46-52 is maintained for the reasons made of record in the office action dated 3/14/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues the claims have been amended. This is not found persuasive because claims 46-52 are to mixtures of ADNFI and ADNFI, which

Art Unit: 1649

was not the elected invention. The elected invention is group I, wherein group I is directed to ADNF I and a method of reducing neuronal cell death by administration of ADNFI.

Claim Rejections - 35 USC § 103

Rejection of claims 1-6, 8-9, and 42-53 under 35 USC § 103(a) is maintained for the reasons made of record in the office action dated 3/14/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant argues that the examiner has failed to provide a reasonable expectation of success and motivation to combine the references. In particular, Applicant argues on page 16 of Remarks that Goodman et al teach away from the use of D-amino acids in an active portion of a conjugate (col 10, lines 31-38). This is not found persuasive because Goodman et al is not teaching that the D-amino acids in the carrier are responsible for inhibiting the active portion of a conjugate. In fact, Goodman teaches that D- or L- amino acids can be used in the carrier, but that the D-forms confer greater resistance to proteolytic activity. Goodman et al is simply saying the carrier could sterically mask or inhibit the active portion of the molecule. That applies to both D- and L- forms of a carrier conjugate. Thus, Goodman et al does not teach away from using D-amino acid substitutions.

Applicant further argues that a post filing date publication by the instant inventors (exhibit 1) suggests substitution from all L- to all D- was expected to yield an inactive form, but instead yielded an active form of ADNF. This is not found to be persuasive because the state of the art at around the time of filing was that substitution of D- for L-

Art Unit: 1649

amino acids in a short polypeptide can and does result in polypeptides with the activity of the L- forms. For instance, Rozhavskaya-Arena et al (2000) found that substituting D- for L- amino acids in a 7-mer (OB3) resulted in many active forms of a synthetic leptin agonist, with various activity levels, that contained one or more D-amino acids. See Table 4, page 2504, and Figure 2, same page. Thus, it is simply a matter of routine testing to determine which substitutions will yield what activities. One of ordinary skill in the art would have had a very high expectation of success.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 1649

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven H. Standley whose telephone number is (571) 272-3432. The examiner can normally be reached on 8:00-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Janet Andre can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Steven Standley, Ph.D.

10/12/06



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER